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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL –2805-0
May 10, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Diana Fickel, RT
Radiology Director
Hocking Valley Community Hospital
601 State Route 664 North
P.O. Box 966
Logan, OH 43138

Facility I.D.#: 116723

Dear Ms. Fickel:

We are writing to you because on April 25, 2000, your facility was inspected by a representative of the State of Ohio, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

> Your facility phantom quality control records were missing for nine weeks in the twelve weekly periods between May 17 through August 10,1999 for your facility mammography unit. Mammograms were performed on patients during nine weeks without the required weekly phantom film checks on the mammography units. **21 CFR 900.12(e)(2)(i)-(iv)**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because the problem identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, the condition represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA

certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the following Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

1. Your records revealed that your facility processed mammograms when the processor quality control records were missing for two consecutive days. **21 CFR 900.12(e)(1)(i)-(iii)**

2. Your records showed that your facility processed mammograms when the processor quality control records were missing six days of 22 days or 27% of total days of operation in October 1999. **21 CFR 900.12(e)(1)(i)-(iii)**

3. One of five random interpreting physician mammography reports did not contain identification of a qualified interpreting physician. **21 CFR 900.12 (c)(1)(iii)**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Ms. Allison Sincek
Ohio Department of Health
Radiologic Technology Section
P.O. Box 118
Columbus, OH 43266-0118

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
Roger S. Ruben, D.O.
Lead Mammography Radiologist
Hocking Valley Community Hospital
601 State Route 664 North
P.O. Box 966
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